

12/544,093

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 09 NOV 2005

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Applicant's or agent's file reference 15270J-98-IPC	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/US04/02856	International filing date (day/month/year) 31 January 2004 (31.01.2004)	Priority date (day/month/year) 01 February 2003 (01.02.2003)	
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 15/85, 15/86; A61K 39/00, 39/395; C07K 5/00 and US Cl.: 530/300, 350, 387.3; 424/130.1, 178.1, 184.1; 435/325			
Applicant NEURALAB LIMITED			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 20 August 2004 (20.08.2004)		Date of completion of this report 27 October 2005 (27.10.2005)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Gregory S. Emch <i>J. Roberts for</i> Telephone No. (571) 272-1600	

Form PCT/IPEA/409 (cover sheet)(April 2005)

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/02856

## Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:  
pages 1-36 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:  
pages 37-46 as originally filed/furnished  
pages\* NONE as amended (together with any statement) under Article 19  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:  
pages 1/2-2/2 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

Form PCT/IPEA/409 (Box No. I) (April 2005)

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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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## Supplemental Box Relating to Sequence Listing

### Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

a. type of material

☒

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☒

on paper

☒

in electronic form

c. time of filing/furnishing

☐

contained in the international application as filed

☐

filed together with the international application in electronic form

☒

furnished subsequently to this Authority for the purposes of search and/or examination

☐

received by this Authority as an amendment\* on \_\_\_\_\_

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/02856**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

**2. Citations and Explanations (Rule 70.7)**

Claims 1, 4-6, 8, 14, 17, 27, 28, 48, 51-53, 55, 61, 64, 74, 75, 96, and 99-102 lack novelty under PCT Article 33(2) as being anticipated by US 2002/0162129 A1 (LANNEFLT, L. ET AL.) 31 October 2002 (31.10.2002). US 2002/0162129 A1 teaches a method of immunization with Abeta fragments for treatment of Alzheimer's disease, pharmaceutical compositions, polynucleotide vaccines, and immunogenic fragments comprising same.

Claims 1, 4-6, 8, 14, 17, 27, 28, 48, 51-53, 55, 61, 64, 74, 75, 96, and 99-102 lack novelty under PCT Article 33(2) as being anticipated by US 2002/0094335 A1 (CHALIFOUR, R. ET AL.) 18 July 2002 (18.07.2002). US 2002/0094335 A1 teaches a method of immunization with Abeta fragments for treatment of Alzheimer's disease, pharmaceutical compositions, polynucleotide vaccines, and immunogenic fragments comprising same.

Claims 1, 4-6, 8, 48, 51-53, 55, 57-58, 96, and 99-102 lack novelty under PCT Article 33(2) as being anticipated by SCHENK, D. ET AL. Immunization with amyloid-b attenuates Alzheimer-disease-like pathology in the PDAPP mouse. Nature 8 July 1999, Vol. 400, No. 6740. SCHENK, D. ET AL. teaches a method of immunization with Abeta fragments for treatment of Alzheimer's disease, pharmaceutical compositions, and immunogenic fragments comprising same.

Claims 1, 4-6, 8, 48, 51-53, 55, 57-58, 96, and 99-102 lack novelty under PCT Article 33(2) as being anticipated by SIGURDSSON, E.M. ET AL. Immunization with a Nontoxic/Nonfibrillar Amyloid-b Homologous Peptide Reduces Alzheimer's Disease-Associated Pathology in Transgenic Mice. American Journal of Pathology August 2001, Vol. 159, No. 2, pages 439-447. SIGURDSSON, E.M. ET AL. teaches a method of immunization with Abeta fragments for treatment of Alzheimer's disease, pharmaceutical compositions, and immunogenic fragments comprising same.

Claims 1, 4-6, 8, 48, 51-53, 55, 57-58, 96, and 99-102 lack novelty under PCT Article 33(2) as being anticipated by LEMERE, C.A. ET AL. Intranasal immunotherapy for the treatment of Alzheimer's disease: Escherichia coli LT and LT(R192G) as mucosal adjuvants. Neurobiology of Aging November/December 2002, Vol. 23, No. 6. LEMERE, C.A. ET AL. teaches a method of immunization with Abeta fragments for treatment of Alzheimer's disease, pharmaceutical compositions, and immunogenic fragments comprising same.

Claims 1, 4-6, 8, 14, 17, 27, 28, 48, 51-53, 55, 61, 64, 74, 75, 96, and 99-102 lack an inventive step under PCT Article 33(3) because inventions lacking novelty do not have an inventive step.

Claims 1, 4-6, 8, 14, 17, 27, 28, 48, 51-53, 55, 61, 64, 74, 75, 96, and 99-102 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 2-3, 7, 9-13, 15-16, 18-26, 29-47, 59-50, 54, 56-60, 62-63, 65-73, 76-95 and 97-98 meet the criteria set out in PCT Article 33(2)-(3) because the prior art does not teach or fairly suggest the claimed invention.

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**Box No. VII**    **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

Claim 48 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: typo in the fifth line.

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

**V.1. Reasoned Statements:**

The opinion as to Novelty was positive (Yes) with respect to claims 2-3, 7, 9-13, 15-16, 18-26, 29-47, 49-50, 54, 56-60, 62-63, 65-73, 76-95, 97-98

The opinion as to Novelty was negative (No) with respect to claims 1, 4-6, 8, 14, 17, 27, 28, 48, 51-53, 55, 61, 64, 74, 75, 96, 99-102

The opinion as to Inventive Step was positive (Yes) with respect to claims 2-3, 7, 9-13, 15-16, 18-26, 29-47, 49-50, 54, 56-60, 62-63, 65-73, 76-95, 97-98

The opinion as to Inventive Step was negative (NO) with respect to claims 1, 4-6, 8, 14, 17, 27, 28, 48, 51-53, 55, 61, 64, 74, 75, 96, 99-102

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-102

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE